Health Information Technology Policy Committee
Final
Summary of the December 13, 2010 Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 19th meeting of the Health Information Technology Policy Committee (HITPC). She reminded the group that this was a Federal Advisory Committee meeting, and was being conducted with the opportunity for public comment. She asked the committee to introduce themselves, and turned the meeting over to HITPC Vice Chair Paul Tang.

2. Opening Remarks

The group approved the minutes from the last meeting by consensus. Paul Tang then reviewed the day's agenda, noting some changes from the printed agenda that was distributed to Committee members.

> **Action Item #1:** Minutes from the November 19, 2010, HITPC meeting were approved by consensus.

3. Governance Workgroup

Governance Workgroup Chair John Lumpkin, who was participating remotely, reminded Committee members that the Governance Workgroup was responding to feedback from presentations it made to the HITPC during the last 2 months. The group prepared two different slide decks: the first deck has just a few slides, showing those recommendations for which they are seeking approval. The second deck includes the background materials, many of which have been viewed by Committee members previously, but revised based on previous HITPC conversations.

He presented the Governance Workgroup's final recommendations in the following areas:

- Nine principles for Nationwide Health Information Network (NW-HIN) governance as preferred approach
- Federal leadership and shared responsibilities
- NW-HIN conditions of trust and interoperability (NW-HIN COTIs)
- NW-HIN validation

- Oversight.

In discussion, the following points were made:

- Paul Egerman discussed the issue of NW-HIN validation and how it relates to the certification process. If a physician purchases a certified system, then there is a reasonable expectation that this certified system will operate on the NW-HIN. He suggested putting forth technical requirements relating to what is involved in meeting the conditions of trust. He asked whether those technical certifications also should necessarily be part of the Workgroup's recommendations. It was suggested that a Venn diagram might best illustrate this issue: any technical requirements pertaining to electronic health records (EHRs) used by physicians would need to be covered in certification. However, there are many types of exchange; some will not be relevant to the individual provider. The Workgroup should examine the certification program and make sure it maps completely to any technical criteria that might apply to the kinds of EHR systems that providers would use.

- John Lumpkin explained that a function of ONC coordination would be to oversee the certification process. Once the conditions of trust and interoperability are established, the next logical step will be to incorporate that into the certification process. Paul Egerman noted that he would like to see it carried a step further, and include it in the Governance Workgroup's recommendations. Purchasers of certified systems, then, should not have to go through a validation process. The other side of this is that the test process for certification should be the identical test in validation. There is a need to ensure that there is coordination between validation testing and certification testing. Otherwise, there will be two different testing approaches, which will lead to a great deal of frustration.

- Deven McGraw emphasized the need to understand the difference between what the federal government can put into law versus what will need to be enforced through meaningful use levers. Where privacy and security issues are concerned, one option would be to suggest that these issues be enforced for everyone, and not just those who are voluntarily participating in the NW-HIN. In some cases, the NW-HIN can be used as an example of best practices. However, it must be made clear which things this group wants to be included in law and which ones are being suggested as best practices. The distinction between what should apply to everyone and what should be included in the voluntary structure needs clarification.

- David Bates noted that he is reluctant to recommend that certification and validation should be identical. They should be coordinated, but it appears that validation is an extension of certification. Things have been certified that did not necessarily include full validation.

- It was noted that the recommendations from this Workgroup must overtly and transparently represent the need for coordination between the certification standards and the work being put forth here. Given the large number of players at the table and the fact that there is an evolution unfolding here, it makes it more imperative that this coordination be in writing.

- The Workgroup agreed to amend the first part of Recommendation 5, as follows (changes in bold italics):

- ONC should establish a mechanism to verify that NW-HIN Conditions of Trust and Interoperability (COTIs) are satisfied.
    - Balance assurance with cost and burden of validation
    - Leverage existing validation methods, processes and entities where appropriate, ***incorporating currently existing testing.***
    - ***EHR certification should include applicable COTIs and EHR cert is a pathway for those COTIs.***

Action Item #2: The amended recommendations of the Governance Workgroup were approved by consensus

4. David Blumenthal's Opening Remarks

National Coordinator for Health Information Technology David Blumenthal welcomed the group, noting that the Governance Workgroup recommendations that were just approved by the Committee illustrate how interoperability will work from a political, social, and economic standpoint. Grantees from all over the country are coming to Washington, DC, and he explained that he was looking forward to the opportunity to interact with them, learn from them, and watch them teach each other. David Blumenthal has been traveling around the country, and finds it enlightening and inspiring to see that there now is a community of people in all states and territories who have signed on to the Health Information Technology for Economic and Clinical Health (HITECH) agenda. They are taking the programs that this Committee is helping to envision, and trying to make them work at the local level.

5. Meaningful Use Workgroup Recommendations

Paul Tang briefly recapped the various hearings that the Meaningful Use Workgroup has convened during the past year as well as other deliberations and final rules that were a part of their deliberative process in creating the recommendations being presented at this meeting.

He noted that today's recommendations are still in draft format. There will be two additional opportunities for discussion; today's presentation is being given prior to the recommendations being released for comment. He and George Hripcsak presented each category of recommendations individually, and opened the floor for discussion of each in turn. In each case, the discussion centered around the proposed stage 2 recommendations.

The recommendation categories were as follows:

- Improve quality, safety, efficiency and reducing health disparities
- Engage patients and families in their care
- Improve care coordination
- Improve population and public health

- Ensure adequate privacy and security protections for personal health information.

The Committee's extensive discussion included these comments:

- One Committee member asked whether Schedule II narcotics were included in these recommendations. It was noted that they currently are not included.

- It was noted that there is no history to use in determining the percentages by which progress can be expected in various areas. With regard to hospital discharge e-prescribing, though, one Committee member commented that just certifying e-prescribing takes months and months.

- Paul Tang explained that the percentages selected to measure progress were chosen to be in between stages 1 and 3. The Workgroup examined Stage 3 and is working towards that goal. In various areas, they are establishing milestones that should be achievable. The Workgroup is planning to look at Stage 1 data as it becomes available and incorporate that learning into its thinking along with the feedback it receives during the comment period.

- In response to a question by Judy Faulkner, Paul Tang confirmed that the same demographics are being used as were used in Stage 1.

- Paul Egerman commented that one lesson learned in the area of patient matching is that the quality of the demographic data has a huge effect. It would be beneficial if the Workgroup could frame its recommendation in this area so that it is objective as to whether or not benchmarks have been met. He suggested having EHRs produce a report, rather than using attestations. Hospitals are nervous having to attest to certain percentages being met, and objective measures would be more helpful.

- Judy Faulkner pointed to the need for more specific language in the recommendation because the term "where appropriate" is vague. The demographics need to be defined, and "appropriate" needs to be defined if vendors are to meet their deadlines.

- David Blumenthal explained that the timeframe for producing regulations for Stage 2 calls for this group making recommendations to the ONC in the summer. Then, the recommendations will undergo the necessary Department of Health and Human Services (DHHS) processes, and then they will be submitted to the White House. The ONC is acutely aware of the need to make this happen as soon as possible, but not so early that it does not take into account the experience of Stage 1.

- Charles Kennedy asked if there was any value in creating a meaningful use measure around cross-cutting measures. Is that being too prescriptive, or is looking at disease state as an organizing principle a good idea?

- David Blumenthal commented that as the Workgroup considers the appropriate percentage number at each stage, one of the clarifying aspects of setting a goal is that in Stage 2, the level set is in some sense the right level to get to Stage 3. Its value is as a step to reaching the

ultimate goal. So, 60% of computerized physician order entry (CPOE) is a stepping stone to getting to 80%. It may be too high or low a step, but the important concept is that it is going in the right direction.

- David Blumenthal remarked that it is possible to mix these particular objectives with a disease-related or problem-related objective. One could even imagine a total reconfiguration of the framework that would give institutions a chance to take a different framework all together. Paul Tang added that the Workgroup discussed this issue and considered the idea that if an institution is doing well, they could test out of the whole process. Neil Calman countered, explaining that this approach would encourage "teaching to the test." They want the system that is created to give everyone an opportunity to tackle the problems germane to their situation. They want to give people the capability to measure and improve on a continuous basis, and that is a counterweight to testing out of the whole situation.

- Gayle Harrell asked about specialty-specific quality issues. Are they going to get to the point where they address specialty measures, and allow specialists to participate? David Blumenthal said that the Quality Measures Workgroup is considering this issue. They are trying to come up with measures that are as robust and practical as possible, but they are always going to be limited by the availability of measures in some specialties. Some specialties have been slower than others in coming up with tested, reliable measures. There will be many more measures available in Stages 2 and 3, but they will have to be practical about whether they will pertain to every conceivable specialty.

- David Lansky noted that Gayle Harrell's sentiment regarding specialty-specific quality issues and measures is shared by the Quality Measures Workgroup. The Workgroup is beginning work in this area by identifying measures that can be applied to all specialists. A solicitation is currently out, and in the next month or so, the Workgroup will be able to see what the existing inventory is. They will identify what cross-cutting measures they will have to use, and what specialty measures there are.

- Judy Faulkner noted that organizations have reduced their alerts because of alert fatigue. Studies show that paring down these alerts results in a much better response. If there are too many, then they lose importance.

- George Hripcsak recognized that the HITPC does not decide what is high priority, but the Secretary of HHS will. Presumably, she will set high-priority conditions based on where there is an addressable gap.

- In response to a question about authenticating, George Hripcsak explained that this is simply listing the source of a piece of information. The EHR has to provide functionality that allows the provider group to display things that meet those criteria. It could connect to a reference source, or use whatever mechanism vendors choose.

- David Lansky said that they should flag the issue of advanced directives. There are no good standards for this today, and this is an area for the HIT Standards Committee to address.

- Judy Faulkner noted that not all e-prescribing vendors have formulary checks, or make them available. This means that the EHR will have to present a formulary check, but many EHRs do not currently include this.

- With regard to sending patient reminders, it was noted that the denominator in Stage 1 is all patients seen within the reporting period. In Stage 3 however, there are two criteria on the denominator: (1) active patients, and (2) those who prefer to receive reminders. The active patient panel would be in denominator, and providers need to reach out and get those people to come in where it is appropriate. That is moving to population health. Patient preference is not whether they prefer to have a reminder; rather, it is whether they prefer to have it electronic or in some other way. Neil Calman pointed out that this also calls out the need to have EHRs record patient preferences regarding reminders.

- Gayle Harrell reminded Committee members that in rural areas and in hospitals, many providers do not have the ability to send labs in a structured manner. The requirement is that labs are sent in a structured manner "where possible." If a lab cannot accept requests in that manner, then that lets the provider out of that requirement.

- Judy Faulkner suggested that it should be a percentage of the labs ordered by the EHR, rather than those just stored there. She is worried about being able to calculate the denominator, given the complications Gayle Harrell mentioned.

- Because meaningful use incentives do not apply to lab vendors, it is hoped that market forces will drive the vendors to provide these features.

- With regard to discharge instructions being given to patients as they leave the hospital, Paul Egerman noted that sometimes patients do not go home; they go to an extended care facility or the like. There is a great deal of transition of care, and patients go back and forth a lot. Another issue is the question of how one measures whether discharge instructions were really offered to the patient.

- Christine Bechtel explained that a number of consumer organizations want to shift the culture so that it is not only the patient but the caregiver who has access to discharge instructions, and so patients and families are offered discharge instructions electronically rather than having to request them. At admission, the hospital could ask about preferences with regard to discharge instructions.

- It was noted that requiring continuity of care documents to be provided within 36 hours undercuts the fact that often it is the first few hours after transfer that are most critical for patient care. Having that documentation at the time of transfer would be valuable, and would reinforce the real definition of meaningful use. There are a variety of different reports and documents relating to continuity of care, and this issue is addressed in provider-to-provider documentation.

- In terms of patient access to their own information electronically, it was noted that 100% of people would have their information available if they chose to access it. Some threshold of

patients are offered that opportunity, and some smaller percentage will actually log in. Mark Probst commented that there are operational aspects of this that worry him, because patients show up at multiple locations, and tracking whether they have been offered the opportunity to access their information electronically is going to be complicated.

- Gayle Harrell questioned the notion of holding the provider accountable for the patient's actions when the provider has no control over whether or not the patient will want to access their information electronically. The functionality has to be there, but the provider cannot be held accountable for patient behavior. Christine Bechtel pointed to some studies that show that provider support is crucial. Without that support there is virtually zero usage of electronic access by patients to their information. With support, they are seeing up to 60% usage. Deven McGraw cited a Pew study showing a high rate of Internet access among all socioeconomic levels, with usage of smart phones and other devices in addition to computers. Another Committee member commented that usage varies widely and that it is something providers must engage with their patients to do.

- Judy Faulkner commented that the definition of a longitudinal care plan is not clear in the Workgroup's recommendations. Unless they define it, she questions whether it should be included. George Hripcsak explained that the Workgroup recognizes this issue, and that Workgroup members have not yet done all the research to come up with a usable definition. They did not want to leave this out of the public comment period, though, because they think it is important, if it can be defined.

- Judy Faulkner asked whether this will push organizations to send their patients to outside, commercial entities that will perhaps not hold their information privately, but will sell it, include advertisements, and not hold to the same privacy and security standards.

- Christine Bechtel said she is not convinced that a personal health record (PHR) is the only thing that these criteria would push the public to. It could be satisfied with a portal or something of that nature. This discussion also points to the broader communications work that the ONC is doing. HHS does not have the authority to regulate non-Health Insurance Portability and Accountability Act (HIPAA) based communication. The U.S. Federal Trade Commission is working on this regulatory framework, so it is not ideal, but there is a growing acknowledgement of need. Patients need to understand their privacy policies, and the ONC is engaged in education efforts on this issue.

- It was suggested that the ONC create a list of frequently asked questions with answers explaining that patients are entitled to a safe download of their information from their provider. If a patient then wants to upload this information to some other PHR vendor or product, then they will need to understand how this information may or may not be used. Christine Bechtel said that they cannot control Microsoft Health Vault's 30-page privacy policy. But they can create plain-language educational material. Judy Faulkner said that most patients will not be able to keep up with this information, given that privacy policies change all the time.

- George Hripcsak suggested that EHRs must have either a secure portal, or if they choose to use the services of a third party, that third party must become a business associate and therefore be subject to the same HIPAA-governed rules as the provider.

- Regarding the three rules about patient use of a PHR record, Marc Probst noted that if a provider builds a database about how patients want to communicate with their physician, that that will create the outcome that these rules seek to create.

- It was suggested that the notion of recording communication preferences be extended to include patient preferences for data sharing. There is a small but vocal minority who want very, very strong limits on data sharing. Most others want more data sharing. Deven McGraw noted that care must be taken in assigning the role they give these preferences in a framework of protecting privacy, and not put technology ahead of privacy policy. There is a need to figure out policy, and then let technology honor it.

- With regard to the recommendations on improving care coordination, David Blumenthal indicated that a forward-learning posture on information exchange will be welcomed by the White House. One of the most consistent comments he gets is that nobody is going to want to exchange information. He encouraged the group to think on this issue more aggressively. There is no current leverage they can exert as a government to encourage exchange other than meaningful use. In that regard, he questions whether one external provider would be sufficient as a requirement in Stage 2, especially if NHIN Direct is by then a meaningful option. Also, he asked whether there needs to be some qualification having to do with the relationship between the parties exchanging information, so that information exchange involves more than just staff members exchanging information within the same health care organization.

- Charles Kennedy reminded the group that there was discussion about administrative requirements being addressed in Stage 2. George Hripcsak pointed to quality management recommendations, which address some clinically oriented efficiency measures. David Blumenthal acknowledged that the final regulation on meaningful use did address the intent to bring administrative requirements back in stage 2. These included electronic billing and claims requirements. Part of the EHR certification is the ability to submit claims electronically. Also, meaningful use talks about billing and demographic information being kept electronically. David Blumenthal noted that this is complicated, because the Accountable Care Act deals with this area, too.

6. Information Exchange Workgroup – Entity-Level Provider Directories (ELPDs) and Individual-Level Provider Directories (ILPDs) Policy Options

Information Exchange Workgroup Micky Tripathi presented a set of three recommendations dealing with ELPDs, noting that at February's HITPC meeting, the Information Exchange Workgroup will present on the issues related to ILPDs. The Workgroup is seeking a dialog on this topic between the HITPC and HITSC to make sure that policy is appropriately manifested in the standards.

The Committee's discussion included the following highlights:

- Jody Daniel asked what mechanism is in place to create a single nationwide registry. Micky Tripathi explained that whether it is a single database or a virtual database that is federated but represents a single registry is a technical, architectural question. Users would see this as a single registry, however. Jody Daniel asked who would be responsible for pulling this together. Paul Egerman explained that nobody has to put it together. It would be published to a single file that multiples authorities would have the right to publish.

- Jody Daniel pointed to the NHIN and meaningful use as ways of getting providers to register. She asked whether the goal is to have a broader net than that. Micky Tripathi explained that the goal is to include everyone, but these are the levers that they have.

- In response to a question from David Blumenthal, Micky Tripathi said that many providers do not feel that an entity-level directory is enough. However, the work is starting here. Hopefully it will demonstrate its value on its own, and create a basis for information that does not exist in a standardized way. It is also hoped that people will start to use it in ways that this group did not imagine.

- David Blumenthal asked about registration and authentication, and how the two relate. Will a registrar have the responsibility of determining that a clinic is, indeed, a real clinic? Micky Tripathi said that this is an area that needs to be considered in the context of other processes. They must ask, how much validation does a certifying authority need to do to issue a certificate? Will this overlap with inclusion in the provider directory? Paul Egerman said that it is likely the registrar would do both.

- Gayle Harrell noted that as a condition of their responsibility and the significant amount of money being given to the states, they could play the role of validating agency and they could be encouraged in the process of creating registrars.

- David Blumenthal encouraged the group to think about the relationship to Medicare and Medicaid. There are major new authorities in the American Accountable Care Act that are asking Medicare and Medicaid to validate providers because of fraud and those types of issues.

> **Action Item #3:** The Committee accepted the recommendations of the Information Exchange Workgroup by consensus.

7. Privacy and Security Tiger Team Update (Patient Matching Hearing)

The focus of this presentation was on the common themes that emerged from the December 9 hearing on patient matching. Recommendations will be presented at a subsequent HITPC meeting. The real interest at the hearing was around information exchange. If a patient at one health care institution is sent to another, how do the two institutions correctly link up that patient's data? There can be false positives and false negatives in data linking. Common themes

ranged from the importance of improving data quality in order to improve matching, and the fact that a universal identifier could be helpful, but would not be a panacea.

Possible areas of future recommendation include the following: (1) transparency (e.g., in terms of algorithms and/or matching rates), (2) accountability mechanisms and addressing liability concerns, (3) developing an evidence base regarding what works, (4) the role of consumers in improving data quality, and (5) propagating corrections.

The Committee's discussion included these points:

- Charles Kennedy described a pilot project in which match rates were increased when they connected the same specific clinical event.

- Art Davidson commented that he likes the idea of consumers playing a role to improve data matching. He noted that in the finance industry, use of the social security number is common. This points back to the Rand study showing that inclusion of a piece of the social security number improves accuracy. Deven McGraw noted that they are prevented from spending money on providing a universal identifier as a solution to this problem, and that is why they did not pursue this line of thinking.

- David Blumenthal noted that there will always be false positives and negatives. Finding the right balance in order to create trust is a communications question, or a psychology question. That will be important when they make recommendations to the committee. He suggested that they learn from the Veterans Administration, Kaiser, and other organizations that already are doing this, what they have settled on as an acceptable compromise.

- Neil Calman suggested that a middle ground might be a "possible" false positive. This could be treated like a medication reconciliation. In some cases it would be valuable to have an opportunity to manually verify a match before it is accepted into the record. The farther one gets away from interaction with the provider, the more potentially dangerous it becomes.

8. Public Comment

- Robin Raiford from Allscripts responded to Paul Tang's comment about decision support and ability to track compliance with that rule. She said that this is in the Centers for Medicare and Medicaid Services' (CMS) final rule, but not in the ONC certified product final rule. She said she would send the exact language to Judy Sparrow. There was a third requirement in the Notice of Proposed Rulemaking language that was dropped in the final rule, unless that was resolved in the CMS FAQs. Also, from the perspective of CPOE, if the intent was "any licensed professional," she suggested that there be a requirement that this be somebody with prescriptive authority, who could respond to the decision support and the alerts as they come up. Finally, if ONC adds eligibility checking in Stage 2 and a requirement to track those alert statistics, the vendors will need more than 4 months to write the code for this.

- Kevin Nicholson with the National Association of Chain Drugstores, offered comments supportive of those made at the last HITPC meeting by the American Hospital Association

(AHA). Similar to the AHA, the National Association of Chain Drugstores has concerns with the Privacy and Security Tiger Team recommendations that seem to conflict with HITECH and HIPAA. With these recommendations, consent requirements may be imposed in future for meaningful use, even though Congress and HHS itself have already rejected such requirements as unworkable.

- Chantal Worzala with the American Hospital Association said that she appreciated the hearing on matching patient data, and was disappointed that they did not get an update on the Enrollment Workgroup, as there could be some interesting overlaps there. The same process of enrollment could be used potentially to form a basis for appropriate and positive patient matching in the care delivery system. As part of that, she encouraged the exploration of a voluntary process for issuing unique IDs. Regarding meaningful use, she is encouraged by the group's commitment to learn from Stage 1 before moving forward. She urged them to give the public sufficient time for comment on the preliminary recommendations. In general, a 60-day comment period is provided for decisions of this magnitude, and she very much encouraged them to offer this length of comment period. Also, she hoped for much more written and evidence-based descriptions of these recommendations.

- Lynn Scheps with SRS Soft said that measures where the denominator is all unique patients in the EHRs is a problem for specialists. An orthopedic surgeon is likely to have thousands of charts of patients who are no longer active. In Stage 2, regarding the proposal of a list of care team members, she suggested avoiding that denominator because it leaves specialists in a position where they cannot meet that measure.

SUMMARY OF ACTION ITEMS:

Action Item #1: Minutes from the October 20, 2010, HITPC meeting were approved by consensus.

Action Item #2: The amended recommendations of the Governance Workgroup were approved by consensus.

Action Item #3: The Committee accepted the recommendations of the Information Exchange Workgroup by consensus.